IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.: 10/790,992
Filed: 03/02/2004
Applicant: Nemenov
For: Portable Laser and Process for Producing Controlled Pain

Declaration under 37 CFR Section 1.131
Proving Invention Prior to Collaboration with Co-Authors

Applicant Mikhail Nemenov declares as follows:

1. I make this declaration in support of my claim that the invention currently claimed according to the amendment filed today in the subject patent application was conceived by me alone prior to my collaboration with the co-authors of the attached paper accepted 1 March 2002 and published in the journal Pain (herein referred to as the Greffrath paper and attached as Attachment 1). My co-authors on the paper were Drs. Wolfgang Greffrath, Stefan Schwarz, Ulf Baumgartner, Hagen Vogel, Lars Arendt-Nielsen and Rolf-Detlef Treede. The claims have been amended to cancel Claim 23 which was derived from my collaboration with Dr. David Clifford Yeomans. Dr Yeomans has consented to his being removed as a co-inventor and a request that he be removed is being filed with the amendment.
2. There has been for several years a need in nerve research to be able to perform experiments in which only a single nerve is stimulated. The potential for use of laser power for nerve stimulation has been known for many years. The separation of nerve endings in human skin tissue varies from about 0.5 mm in tissue such as fingertips to a few centimeters in regions of the back. In most regions of the skin the nerve endings are separated by about 1 to 3 mm. Therefore, in most skin regions, if the laser power is insufficient, too much time is required to provide enough energy to stimulate a single nerve and the laser energy dissipates affecting multiple nerves. YAG:Nd lasers have been available for many years that have sufficient power to stimulate single nerves with a properly focused beam.
3. During the period 1994-1995, I performed experiments with a YAG:Nd laser operating at 1,060 nm to evoke single cell (monomodal) sensations (including pain sensations). The results of these YAG:Nd lasers clearly demonstrated that single nerves could be stimulated with the pulsed laser beam from these YAG:Nd lasers. Results of these tests were not published. YAG:Nd lasers of the type I used were large (about 1 m X 0.3 m X 0.3 m) and heavy (about 100 kg) and expensive (about ($ 60,000). Diode lasers are at that time were easily portable and cost only about $ 10,000.
4. During the period 1996 – 1997 diode lasers with sufficient power to stimulate single nerves became available and I developed a 20 W diode laser device. Six volunteers were tested in facilities of my lab at Pavlov Medical University in Saint Petersburg, Russia during the period Dec 1996 to April 1997. With these test I was able to confirm in Russia my concept of producing single cell

stimulation with a small relatively low cost diode laser. This was my first actual reduction to practice of my concept of using diode lasers for single nerve stimulation. The results of these experiments were not published but the results were discussed privately at a workshop that I helped organize in May 1997 at Pavlov Medical University. A copy of workshop agenda is attached as Attachment 2. My oral presentation is referred to at Section 3.2.

5. At the May 1997 workshop I met Dr Arendt-Nielsen who operates a research laboratory in Denmark that is well-known for its nerve research. I proposed to him formal experiments to confirm my earlier results that the relatively inexpensive diode lasers could be used for monomodal skin experiments and Dr. Arendt-Nielsen faxed me a formal invitation to apply for work permit in Denmark.
6. During the period January – April 1998, I developed specifications, protocol and tested a prototype diode laser in preparation for formal nerve research on volunteers at Dr. Arendt-Nielsen's lab. This preliminary project was funded at my own my expense. During January 1998 I contacted IRE Polus, a laser company and requested specifications for various models of their diode lasers. A copy of response of laser company IRE-Polus to my request is attached as Attachment 3.
7. In May 1998 Dr. Arendt-Nielsen invited me to conduct experiments in his lab in Aalborg, Denmark. He agreed to pay for the parts for a new laser built to my specifications. The parts for the diode laser for Dr. Arendt-Nielsen lab were ordered in April of 1998 from IRE-Polus. The confirmation of order was done in the June of 1998. Attachment 4 is a copy of an invoice for the parts.
8. During the period July – December 1998 the diode laser for Dr. Arendt-Nielsen lab was fabricated, tested and applied to volunteers. I supervised a student of Aalborg University who developed interface software in accordance with protocols that I developed that simplified the stimulation set up. About 30 volunteers were tested at the Arendt-Nielsen laboratory but these experiments were cancelled before results good enough to be reported in scientific literature could be obtained.
9. In November-December of 1998. I contacted Dr. Treede who directs a research laboratory in Main University in Denmark and suggested that I would like to perform nerve stimulation studies in his laboratory. . A copy of my initial email and his response is attached as Attachment 5. I told him I thought I could prove that diode lasers could be used to produce single monomodal sensation in skin and activation of single nerve in vitro. We agreed that I would provide the laser and protocol. Dr. Treede asked when I could have a laser ready to use in the study. I told him that I could have a laser and protocol by the end of July 1999. The preparation of the laser and the protocol was funded at my own expense.
10. Dr. Treede arranged for a travel grant to support my travel and to cover lodging for the experiment. During September 16 – 28, 1999, I performed nerve experiments in Dr. Treede's laboratory with my diode laser. My work was a part of a team of researchers including Drs. Baumgartner, Vogel, Schwartz and Greffrath who were all employees or otherwise affiliated with Dr Treede's laboratory. Dr. Baumgartner was not present at the actual experiments but he processed EEG laser evoked potentials in human experiments. Dr. Vogel

supervised the recording of EEG/LEP data in accordance with a protocol I developed. The actual recording of the data was by a technician in the laboratory whose name I do not remember. The recording of the data was accomplished in one day. Dr. Schwartz prepared and assembled a calibrations patch for use in experiments. Dr. Greffrath prepared all nerve cells and tested the cells to determine if they were capsaicin sensitive. I applied the laser to the cells. These in vitro experiments took about 5 days because for statistically proven data we need about 6-8 capsaicin sensitive cells. Dr. Greffrath wrote most of the 2002 paper published in the journal Pain. A copy of the paper (as previously stated) is attached to this declaration as Attachment 1. The work was supported by a grant as explained in the last sentence of the Pain paper. My travel grant was from a Germany academic fund (DAAD grant) as a visiting professor. This was the second actual reduction to practice of my concept of using diode lasers to produce single nerve stimulation. During the period between my first actual reduction to practice (in December 1996 to April 1997) and the second September 1999 reduction to practice my efforts to prove that diode lasers could be used for single nerve stimulation were continuous and diligent.

11. In October 2000 I moved to the United States and was employed at Sparkolor Corp which at the time was developing diode lasers. I applied for Permanent Residency in the United States. In support of my application for a "Green Card" Dr. Treede wrote a letter setting forth facts relating to my earlier pain research using diode lasers. A copy of that letter is attached as Attachment 6. My effort to promote the use of diode lasers for single nerve stimulation has been continuous and uninterrupted since diode lasers first became powerful enough for this use in the 1996 period.
12. After the work at the Treede laboratory was completed, I continued to develop procedures for nerve stimulation with my diode laser. During the period from September 2002 to March 3, 2003 I collaborated with Dr David Clifford Yeomans. We conducted rat experiments similar to some of the experiments in the Treede laboratory. That collaboration resulted in improvements to the processes that I had first reduced to practice during the period Dec 1996 to April 1997 that had been utilized in work at the Arendt-Nielsen and Treede laboratories. Specifically Dr. Yeomans contributions led to the specific improvements relating laser pulse energy, timing and duration. These improvements were claimed in Claim 23. This claim has been cancelled and a request to remove Dr. Yeomans as a co-inventor is being filed along with the amendment and this declaration. This action is being done to simplify what is the claimed invention and to simplify the timing of the conception of the invention.
13. In February 2003 I contacted a San Diego patent attorney, John R. Ross who assisted me in preparing a provisional patent application on March 3, 2003 and on March 2, 2004 he filed on my behalf the present patent application.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U. S. C.

1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

X _____ 01/08/2007

Michael Nemenov Date